

REMARKS

Claims 1-32 are pending, with claims 1, 17, 18, and 21 being independent.

35 U.S.C. §112, Second Paragraph Rejection

The Examiner has rejected claims 1-16 and 21 as being indefinite. Applicant requests withdrawal of this rejection because applicant has amended the claims for clarity.

35 U.S.C. §102(b) Rejection

The Examiner has rejected claims 1, 9-12, 16, 21, and 23 as anticipated by U.S. Patent No. 5,702,397 (Goble).

Independent claim 1, as amended, relates to a bone anchor including an anchor body configured to be retained within bone. The anchor body defines a path for passage of a member through the anchor body and includes a restrictor defining an opening having a first portion permitting passage of the member therethrough, and a second portion restricting passage of the member therethrough. The restrictor is configured such that movement of the member between the first and second portions is not in a direction of passage of the member along the path through the anchor body.

Independent claim 21, as amended, relates to a method including placing a bone anchor in bone. The bone anchor defines a path for passage of a member through the bone anchor and includes a restrictor defining an opening having a first portion for permitting passage of the member therethrough, and a second portion restricting passage of the member therethrough. The method includes moving the member between the first and second portions not in a direction of passage of the member along the path through the anchor body.

Applicant requests withdrawal of this rejection at least because Goble fails to describe or suggest the claimed restrictor or movement.

The Examiner's rejection states, in part:

As most clearly illustrated in Figure 23, a bone anchor (135) includes a unitary central body and a restrictor. The anchor includes a plurality of bone penetrating

tips (137). An opening (140) has a first portion (143) permitting passage of a member (27) and a second portion (144) restricting passage. The member (27) is moved between the first portion (143) and second portion (144) in direction non-parallel and substantially perpendicular to the direction of passage through the opening. Goble explains that the member (27) can be pulled through the first portion freely in one direction, but is locked in place if pulled in the opposite direction (column 11, line 61 through column 12, line 42).

However, Goble does not describe or suggest an anchor body or bone anchor defining a path for passage of a member through the anchor body or bone anchor, and a restrictor configured such that movement of the member between first and second portions is not in a direction of passage of the member along the path through the anchor body, as now claimed in claim 1, or a method including moving a member between first and second portions not in a direction of passage of the member along the path through the bone anchor, as now claimed in claim 21. Rather, in Goble, the suture 27 merely moves in a direction of passage of the member along the path through the anchor, i.e., along the path defined through holes 143 and 144 and cavity 140. In particular, though the part of suture 27 spanning between holes 143 and 144, i.e., the part of the suture within proximal cavity 140, is not parallel to the parts of the suture within holes 143 and 144, all parts of the suture in Goble only move in the direction of passage of the member along the path in the anchor that the suture takes to pass through the anchor.

This is in contrast to applicant's claimed invention. For example, referring to FIG. 5 of applicant's specification, a member 10 moves between portions 227 and 235 by movement (up and down as shown in FIG. 5) which is not in the direction of passage of the member along the path through the anchor body (the path running side to side as shown in FIG. 5).

Therefore, applicant submits that claims 1 and 21, and there dependent claims, are patentable over Goble for at least the reasons discussed above.

35 U.S.C. §103(a) Rejection of Claims 2-7, 18-20, and 22

The Examiner has rejected claims 2-7, 18-20, and 22 as being obvious over Goble in view of U.S. Patent No. 6,066,160 (Colvin).

The Examiner's rejection states:

Colvin gives support for including this suture locking mechanism as part of another device in lines 5-7 of column 8, as the main member may be incorporated as part of another prosthetic device, which could be a bone anchor. It would have been obvious to one of ordinary skill [in] the art at the time the invention was made to substitute the suture locking edges of Colvin for the locking ball in the bone anchor of Goble, as this is an alternate way to prevent sutures from passing in an undesired direction through a device.

Applicant submits that the Examiner has failed to establish a *prima facie* case of obviousness. The law of obviousness is not whether something could be modified, but whether there is a suggestion or motivation in the references for the proposed modification. "The fact that a prior art device could be modified so as to produce the claimed device is not a basis for an obviousness rejection unless the prior art suggested the desirability of such a modification." *In re Gordon*, 733 F.2d 900 (Fed. Cir. 1984). Just because something may be an alternate way of doing something does not establish a *prima facie* case of obviousness.

There mere fact that Colvin states that the suture locking mechanism can be included as part of another device does not provide a suggestion or motivation for modifying Goble's structure to include locking edges rather than a locking ball. At column 8, lines 5-7, Colvin suggests that main member 12 can be incorporated into a prosthetic device as illustrated in FIG. 4. As shown in FIG. 4, it is the entire device 10 that is incorporated into a valve 30. There is no suggestion in Colvin to support incorporated only Colvin's locking edges in another device, let alone substituting Colvin's locking edges for a locking mechanism already in another device.

Furthermore, the Examiner is impermissibly applying hindsight, using applicant's invention as a template and picking and choosing among the elements of Colvin to recreate the claimed invention.

Therefore, for at least the reasons discussed above, applicant submits that claims 2-7, 18-20, and 22 are patentable over Goble in view of Wenstrom.

35 U.S.C. §103(a) Rejection of Claim 8

The Examiner has rejected claim 8 as being obvious over Goble in view of U.S. Patent No. 5,782,866 (Wenstrom).

Applicant submits that Wenstrom does not overcome the deficiencies in Goble discussed above. In particular, Wenstrom fails to describe or suggest the claimed restrictor or movement.

Therefore, for at least this reason, applicant submits that claim 8 is patentable over Goble in view of Wenstrom.

35 U.S.C. §103(a) Rejection of Claims 13-15, 17, and 24

The Examiner has rejected claims 13-15, 17, and 24 as being obvious over Goble in view of U.S. Patent No. 6,149,669 (Li).

Regarding claims 13-15, which depend from claim 1, and claim 24, which depends from claim 21, applicant submits that Li does not overcome the deficiencies in Goble discussed above. In particular, Li fails to describe or suggest the claimed restrictor or movement. Therefore, for at least this reason, applicant submits that claims 13-15 and 24 are patentable over Goble in view of Li.

Independent claim 17, relates to a tissue repair system including two bone anchors coupled by a flexible member. The Examiner's rejection states:

Goble includes all the limitations of claims 17 and 24, but fails to connect a second bone anchor to the first bone anchor with a flexible member. As illustrated in Figures 1-5, Li teaches that multiple bone anchors can be attached by a flexible member, or suture (60). This system eliminates the cumbersome process of threading and manipulating sutures (column 1, lines 38 and 55). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use anchors of Goble in a system where multiple anchors are connected by a suture, as taught by Li, as this overcomes the complications associated with threading sutures.

Applicant submits that there is no suggestion or motivation for the proposed combination. Goble is directed to a bone anchor for mounting a ligament graft in a bone tunnel, e.g., for ACL reconstruction. In use, the surgeon seats the bone anchor in the bone tunnel, and pulls a suture or shaft attached to one end of the ligament graft through the seated bone anchor to apply tension to the graft. To maintain the applied tension on the graft, the bone anchor includes a clamp that prohibits the suture or shaft from being pulled back through the bone anchor. The other end of the ligament graft is secured in another tunnel section or adjacent bone cortex surface, e.g., as shown in Fig. 8 of Goble, by a screw 28 that travels into the bone end 16 of the ligament graft.

In contrast, Li is directed to an assembly for suturing ligaments or muscles to a bone surface, e.g., for rotator cuff ligament repair. In Li, the surgeon places multiple anchors in multiple respective holes in bone. The multiple anchors are coupled together by suture pre-tied at a fixed length. The suture spans between the anchors acting to hold ligament or muscle laid over the bone surface to the bone.

The references do not provide a suggestion or motivation to one skilled in the art to use Goble's anchor in a system where multiple anchors are connected by a suture as taught by Li. Goble describes the use of a single anchor in applications where a graft is secured within a bone tunnel. Neither references describes or suggests using two of Goble's anchors in such an application, or using Goble's anchor in an application where a ligament or muscle is secured to the surface of bone, as described in Li. Thus, neither reference provides a suggestion or motivation for coupling two or more of Goble's anchors with suture. Furthermore, overcoming complications associated with threading sutures, as posited by the Examiner, does not provide a motivation for the proposed combination. Goble is directed to a system that allows the surgeon to pull suture to apply tension to a graft. Joining multiple anchors of Goble with suture as taught by Li would destroy this feature of Goble, making the anchor of Goble unsuitable for its intended purpose.

Therefore, for at least the reasons discussed above, applicant submits that claim 17 is patentable over Goble in view of Li.